



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT 28 1997

0814 '97 DEC 16 P1:43

Mr. Rakesh M. Amin
Dilling and Dilling
150 North Wacker Drive
Chicago, Illinois 60606

Dear Mr. Amin:

This is in response to your letter of October 20, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), on behalf of Nutrition for Life International, Inc., Houston, Texas. Your submission states that Nutrition for Life International, Inc. is making, among other claims, the following claims for the following products:

Phytogreen

"Wheat grass nutritionally helps the body resist harm from X-rays, radiation therapy and air pollution"

GS 1500

"May nutritionally help reduce pain and inflammation and improve connective tissue elasticity and cushioning"

CMO CIS-9 with with [sic] P-5-P

"May nutritionally help provide lubrication to joints and bones, may nutritionally modulate the immune system, and may nutritionally relieve pain and inflammation"

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate disease, namely, as an adjunct to radiation therapy (Phytogreen) and, in the context of the information presented in the claims for the products "GS 150" and "CMO CIS-9 with with [sic] P-5-P", as treatments for the pain, inflammation, and other symptoms of arthritis and/or degenerative joint and bone diseases. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that these products

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are intended for use as drugs within the meaning of section 201(g)(1)(B) of the act, and that they are subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Dallas District Office, Office of Compliance, HFR-SW140

DILLING AND DILLING
ATTORNEYS AT LAW
150 NORTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
(312) 236-8417

KIRKPATRICK W. DILLING
KAREN A. WEAVER, R.PH.
RAKESH M. AMIN, R. PH.

ESTABLISHED 1917

ALBERT W. DILLING
1892 - 1969
JOHN M. MANN
PATENT AND TRADEMARK
COUNSEL

October 20, 1997

0815 '97 DEC 16 P1:43

Office of Special Nutritionals (HFS-450)
Center for Food Safety and
Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Via Overnight Delivery

Re: Notification of Statements of Nutritional Support

Dear Sir:

Enclosed is the original and two copies of an executed notification of Statements of Nutritional Support as required under Section 101.93 of 21 Code of Federal Regulations.

If necessary, please address future correspondence to our firm.

Sincerely yours,

DILLING AND DILLING



Rakesh M. Amin

Enclosure

REC'D VCD
OFFICE
NUTRITION
'97 OCT 24 10:00

75560 CALLE DEL SUR
INDIAN WELLS, CALIFORNIA 92210
(619) 568-1924
TELEFAX NO.
(619) 341-1045

CALIFORNIA LEGAL ASSOCIATE
R. CHANDLER MYERS
301 NORTH LAKE AVENUE
PASADENA, 91101
(818) 792-0007



TELEFAX NO
(312) 236-8418

CABLE ADDRESS
DILGRON

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October 20, 1997

Office of Special Nutritionals (HFS-450)
Center for Food Safety and
Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

97 OCT 24 10:18
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Re: Statements of Nutritional Support

Dear Sir:

Consider the following as notification of Statements of Nutritional Support as required under Section 101.93 of 21 Code of Federal Regulations.

Distributor Name & Address: Nutrition For Life International, Inc.
9101 Jameel
Houston, Texas 77040

<u>Statement Text</u>	<u>Name of Subject Dietary Ingredient(s)</u>	<u>Brand Name</u>
1) "Advanced Formula Supplement For Total Health"; "Supplement for proper growth and health"; and "Vitamin B-6, Vitamin B-12, folic acid, copper, iron and zinc help the body manufacture immune support cells which work to ward off various conditions of ill health".	Vitamin A, Vitamin D, Vitamin E, Vitamin C, Vitamin B-1, Vitamin B-2, Niacin, Pantothenic Acid, Vitamin B-6, Vitamin B-12, Folic Acid, Biotin, Magnesium, Potassium, Zinc, Copper, Manganese, Iodine, Chromium, Selenium and Choline	Master-Key Plus
2) "Can nutritionally help the human body to maintain the vital processes of oxidation, secretion, growth and regeneration" and "may help reduce the effects of everyday stress".	Honeybee Pollen, Fructose, Montmorillonite (Trace Mineral Compound), Vitamin C, Rose Hips, Honeybee Propolis.	Nutra/Gold Honeybee Pollen with Propolis
3) "Nutritionally assists in general cleansing" and "provides nutritional support for numerous functions of the colon, liver, kidneys and lymphatic glands".	Garlic, Saw Palmetto, Fenugreek, Quassia, Red Sage, Yellow Dock, Black Cohosh, Dandelion Root, Cascara Sagrada Bark, Suma	Herbal Blend 2
4) "Supplies nutrition designed for the respiratory system".	Slippery Elm, Foenugreek, Wild Cherry, Thyme, Pleurisy Root, Marshmallow, Saw Palmetto, Mullein, Capsicum, Yerba Santa	Herbal Blend 3

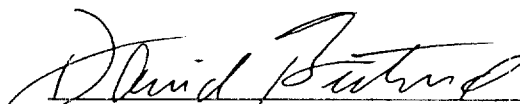
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<u>Statement Text</u>	<u>Name of Subject Dietary Ingredient(s)</u>	<u>Brand Name</u>
23) "Nutritionally necessary for the makeup of Coenzyme A which helps activate the cellular metabolism of carbohydrates, fats and proteins"; and "Pantothenic Acid is considered essential for the synthesis of cholesterol and fatty acids".	Pantothenic Acid	Pantothenic Acid Plus
24) "Nutritionally provides energy and promotes physical and mental performance"; "Nutritionally helps body maintain long term health"; "Barley Grass nutritionally aids the body in DNA repair and helps improve stamina and clarity of thought"; "Wheat Grass nutritionally helps the body resist harm from X-rays, radiation therapy and air pollution"; "Spirulina helps neutralize free radicals that damage healthy cells"; "Ginkgo Biloba is a nutritional circulatory stimulant"; "Siberian Ginseng is a nutritional circulatory stimulant"; and "Grape Seed Extract provides an antioxidant role".	Wheat Sprout Concentrate, Barley Grass Juice Powder, Wheat Grass Juice Powder, Spirulina, Acerola Berry Juice Powder, Nova Scotia Dulce, Royal Jelly, Siberian Ginseng Extract, Ginkgo Biloba Extract, Green Tea Extract and Grape Seed Extract	Phytogreen
25) "Vitamins C, B1 and A are nutrients known to be antioxidants".	Vitamins C, B1 and A	Oraflow Plus
26) "To help nutritionally support the epidermal system"; and "For nutritional skin care".	Vitamin A (Fish Liver Oil), Vitamin D (Cholecalciferol), Vitamin E (dl-Alpha Tocopheryl Acetate), Vitamin C (Ascorbic Acid), Vitamin B1 (Thiamine Mononitrate), Vitamin B2 (Riboflavin), Vitamin B6 (Pyridoxine HCl), Vitamin B12 Folic Acid, Niacin (Niacinamide), Biotin and Zinc (Zinc Sulfate)	Nutique Multivitamin Supplement with Zinc
27) "Supplies antioxidant nutrients and free radical scavengers".	Vitamins A, B2, C and E	Deox
28) "B Vitamins nutritionally essential for turning food into energy".	Vitamins B1, B2, B6 and B12	B-Complex Mega Formula
29) "May nutritionally support mental performance".	Vitamins C and B12, Folic Acid, Potassium and Gotu Kola	Alert

<u>Statement Text</u>	<u>Name of Subject Dietary Ingredient(s)</u>	<u>Brand Name</u>
41) "Contains antioxidants which help control cell-damaging toxins"; "Contains minerals nutritionally essential for bone function and the digestion of food and transportation of oxygen throughout the body"; "Contains amino acids which are building blocks of proteins"; and "May keep children healthier and nutritionally build strong immune systems".	Beet, Carrot, Parsley, Tomato, Broccoli, Spinach, SuperNutri-Green™, Wheat Grass, Barley Grass, Soy Grass, Papaya, Apple, Beta-Carotene (A), Vitamin C and Vitamin E	NutriBuddies
42) "Nutritional support for the normal growth and repair of connective tissue, joints and articular cartilage"; "May nutritionally help rebuild joints, tendons, cartilage and soft tissue"; and "May nutritionally help reduce pain and inflammation and improve connective tissue elasticity and cushioning".	Glucosamine Sulfate and Manganese Sulfate	GS 1500
43) "P-5-P, a form of Vitamin B6, is nutritionally essential for amino acid metabolism, neurotransmitter synthesis and glycogen breakdown"; and "May nutritionally help provide lubrication to joints and bones, may nutritionally modulate the immune system, and may nutritionally relieve pain and inflammation".	Cerasomal-Cis-9-Cetylmyristoleate and Pyridoxal Phosphate (P-5-P)	CMO CIS-9 with with P-5-P
44) "Beneficial bacteria for nutritional support of the colon".	Lactobacilli Acidophilus, Rhamnosus, Bifidus, Bulgaricus, Caucasicus and Yoghurti	Alkadophilus
45) "Provides natural nutrients to support adrenal gland function".	Raw Adrenal Concentrate, Vitamin C, Pantothenic Acid, Zinc, Manganese and Niacinamide	Adrenergy
46) "To maintain and strengthen nutritional health"; and "Alkalizes your body naturally".	Barley Juice Concentrate	Alka-Green

<u>Statement Text</u>	<u>Name of Subject Dietary Ingredient(s)</u>	<u>Brand Name</u>
50) "May reduce stress in the body and aid digestion".	Pancreas, Ox Bile, Papaya Enzyme, Duodenum, Liver, Betaine, Bromelain, Vitamins B1 and B2, Niacinamide, Anise, Peppermint and Chamomile	Alka-Pan
51) "Helps in the digestion of milk and dairy products" and "Aids the stomach's digestive process and may acidify the stomach".	Amylase, Protease, Lipase, Cellulase, Lactase, Papaya Enzymes (Papain), Pineapple Enzymes (Bromelain) and Alfalfa Powder	Super Digest

The information contained in this notice is complete and accurate. The above distributor has substantiation that the statements are truthful and not misleading.



David Bertrand
CEO/President
Nutrition For Life International, Inc.